Election/Restriction

1. Applicant's election of Group I, encompassing claims 1-8, 13-15 and 17-20, in the reply, filed on March 14, 2008, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the Restriction requirement, filed on February 19, 2008, the election has been treated as an election without traverse (MPEP § 818.03(a)). The inventions contained in groups II and III, encompassing instant claims 9-12, 16 and 21-25, are withdrawn from consideration as being drawn to non-elected subject matter. See 37 CFR 1.142(b). Accordingly, the subject matter now under consideration is drawn to claims 1-8, 13-15 and 17-20.

The restriction having been made without traverse is herein made FINAL.

Priority

2. This application claims priority of International Application PCT/US03/20154, filed June 26, 2003, which claims priority to Provisional Patent Application 60/401,220, filed August 5, 2002.

3. It is noted that this application appears to claim subject matter disclosed in prior Application PCT/US03/20154, filed June 26, 2003, which claims priority to Provisional Patent Application 60/401,220, filed August 5, 2002. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the

prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the

claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Information Disclosure Statement

4. The Information Disclosure Statement (IDS) correspondence submitted by Applicant on May 31, 2005 is acknowledged. The references have been reviewed to the extent each is a proper citation on a U.S. Patent.

5. The Information Disclosure Statement filed May 31, 2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all

other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Specifically, the documents WO 99/32127, WO 03/009784 and WO 03/009774 have not been provided.

Appropriate action is required.

Specification

Abstract

6. The abstract of the disclosure is objected to because the abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text. Correction is required. See MPEP § 608.01(b).

7. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The

abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because the abstract provides too short a narration to adequately convey Applicant's proposed invention. Correction is required. See MPEP § 608.01(b).

8. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specifically, the list of references provided on page 12 of the instant specification have not been considered unless cited by the examiner on form PTO-892. The reference by Seddon has not been provided.

Claim Rejections - 35 USC § 101 and 35 USC § 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 14-15 and 17-20 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

It is unclear from the instant claim language whether Applicant intends for the claims to be a process or a composition.

10. Claims 14-15 and 17-20 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

11. Claims 14-15 and 17-20 are provides for the use of anecortave acetate, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

12. Claims 14-15 and 17-20 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process

claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

13. Claims 14-15 and 17-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language "pharmaceutically effective amount" in claims 1 and 5 is indefinite. The Examiner is unable to ascertain from the instant specification what the term "pharmaceutically effective amount" encompasses. Without further disclosure from

Applicant, the phrase is unclear and confusing.

15. Claim 1 recites the limitation "the loss," “the compound,” and “the prevention” in the instant claim. There is insufficient antecedent basis for these limitations in the claim.

16. Claims 1-4 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

“To prevent”, as defined by Merriam-Webster Dictionary is to keep from happening or existing, which implies taking advance measures against something possible or probable. Furthermore, the definition of “to prevent” and the “act of preventing” embraces the complete 100% inhibition. Thus, the burden of enablement in the assertion of this claim is much higher than would be the case of enabling the treatment of the condition and is not achieved. Nowhere in the prior art or instant application has anecortave acetate been shown to prevent the loss of visual acuity associated with AMD.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark (US Patent 5,679,666 and cited by Applicant), in view of Yaacobi (US Patent 6,416,777 and cited by Applicant).

Clark teaches the use of anecortave acetate or its free alcohol (column 3, lines 42-45) for the treatment of macular degeneration (column 3, lines 50-51).

Clark does not teach the administration methods of juxtascleral injection or implant, intravitreal injection or implant *or* a pharmaceutically effective amount.

Yaacobi teaches the administration of angiostatic steroids, such as anecortave acetate (column 7, lines 29-31) to the posterior segment of the eye for the treatment of age-related macular degeneration (AMD) (column 1, lines 17-19). Yaacobi teaches AMD attacks the center of vision and blurs it, making reading, driving and other detailed tasks difficult or impossible (*i.e.*, affects the visual sharpness, acuteness, acuity, keenness, etc. of the individual) (column1, lines 23-27). Yaacobi et al. teaches the dosage can be in the form of a solution, suspension, powder or combination (column 6, lines 11-13). Yaacobi describes the insertion of the active ingredient in a depot (specifically anecortave acetate by incorporation by reference (column 8, line39)) in a juxtascleral position just above the macula (column 7, line61 to column 8, line 40). Yaacobi teaches the depot can deliver a pharmaceutically effective amount of active ingredient for years. Yaacobi teaches important physicochemical properties need to be assessed like hydrophobicity, solubility, dissolution rate, diffusion coefficient, etc. (column 8, lines 52-59).

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in

that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.). In the normal course of events from drug discovery to marketization of a drug product, certain steps and principles are followed, all within the constrains of the world's drug regulating authorities and in the interest of *quaere verum* of science, that establish trust that the product is safe and efficacious. Once a prospective drug substance is identified to have a therapeutic effect for a disease/condition/disorder and prospectively shows promise as a treatment for a malady it must be then tested pharmacodynamically and finally tested pharmacokinetically (*e.g.*, describes the relationship between dose and concentrations of a drug in a reference fluid or tissue). The various pharmacokinetic parameters (*e.g.*, adsorption, distribution, metabolism and excretion) are routinely assessed in the evaluation of a drug substance to assure its safety and efficacy. Therefore, no more than routine experimentation would have been necessary to one of ordinary skill in the art at the time of the invention once the therapeutic concentration efficacious at the treatment site had been determined. Therefore, no more than routine optimization would have been necessary to one of ordinary skill in the art at the time of the invention to determine the exposure over time, the instantaneous exposure in the eye needed to elicit a therapeutic effect and dosage amounts.

It would have been obvious to one of ordinary skill in the art at the time of the invention that visual acuity related to age-related macular degeneration could be maintained via the administration of a therapeutic amount of anecortave acetate to the posterior segment of the eye. The posterior segment of the eye specifically addressed

by Yaacobi is a juxtascleral position just above the macula and would be deposited as a depot of active ingredient, such as anecortave acetate, therefore rendering instant claims 5-8 obvious.

Therefore, the teachings of Clark, in view of Yaacobi, render the claimed invention obvious.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory

double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

U.S. Patent Application 10/606,501

18. Claims 5-8 are rejected on the ground of nonstatutory double patenting over claims 5-6 and 8 of U.S Non- Provisional Application No. 10/606,501. Although the conflicting claims are not identical, they are not patentably distinct from each other because reference claim 5 discloses a method for maintaining visual acuity in a person with AMD by giving the patient between 3-30 mg of anecortave acetate via the same administration routes, thus rendering instant claims 5 and 7 obvious. Reference claim 6 discloses administration of a juxtascleral depot which is the same limitation as instant claim 6, thus rendering instant claim 6 obvious. Reference and instant claim 8 have the same limitation of 15 mg of active ingredient in the depot, thus rendering instant claim 8 obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claims allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Kudla whose telephone number is (571) 270-3288. The examiner can normally be reached on 9am - 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Joseph S. Kudla/
Examiner, Art Unit 1611
June 4, 2008

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615